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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,352	10/08/2003	Kyoji Ogoshi	3190-044	8311

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EXAMINER	
LEARY, LOUISE N	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,352	OGOSHI, KYOJI	
	Examiner	Art Unit	
	Louise N. Leary	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-18-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CC

1. Claims 1-18 are pending in this application.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a screening method to determine effective cancer treatment medicines, does not reasonably provide enablement for determining "effective cancer *curative* medicines". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not provide sufficient support for making or using an effective cancer *curative* medicine. It is noted that Webster's Dictionary (Copyright © 1984, 1988, 1994) defines "*curative*" as "[1. serving or tending to cure. 2. Of or relating to the cure of disease. –n. A remedy....]" See column 2 on page 336.

Thus, the specification provides support for screening and treating cancer but does not provide sufficient support for curing cancer. Therefore, the scope of the instant claims is not commensurate with the scope of the enabling disclosure.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all occurrences, the claims are indefinite because it is unclear if the limitations in the parenthesis are part of the subject matter claimed. Specifically, it is unclear if "(prognosis, treatment effects)" is part of the instant claim limitations. It is suggested that the parenthesis be deleted from the instant claims to comply with US Patent practice.

In all occurrences, the claims are indefinite due to the grammatically improper use of the phrases "have been determined"; "have been analyzed"; and "have been used". Correction is required to comply with US Patent practice.

Claims 1, 11, 13, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (1) a step describing in vitro and/or in vivo screening to determine effective cancer curative medicines; and (2) a step correlating "the marker" with *the effectiveness of a cancer curative medicine* determined by the instant screening method.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a host or samples obtained from a host.

Claim 7 is indefinite because the metes and bounds intended for the phrase "under a condition in which the interaction is possible" can not be determined.

Claims 17-18 are indefinite because "[the specified positions and the amino acids together with the base sequences have been used as a marker]" does not particularly point out chemical reactants in the instant "[Clinical measuring reagents comprising a composition:]".

Claim 15, line 5, recites the limitation "wherein the variation of polymorphic positions" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The omitted elements are:. all chemical reactants in the instant "[Clinical measuring reagents comprising a composition:]".

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santamaria et al (US 5,972,604).

Santamaria et al disclose a method for determining the nucleic acid sequence of one or more polymorphic genes. With respect to the instant method steps, Santamaria et al disclose the "[...method provides overlapping sequence data comprised of only the copies of the locus of interest as is exemplified by each of the types of HLA loci.]". See column 3, lines 25-51. Regarding the evaluating cancer treatments as claimed, Santamaria et al disclose "[...a method for determining genetic polymorphism at one or more genetic loci of interest which can be employed, for example in HLA typing, detection, evaluation, and/or characterization of genetic disease such as, for example sickle cell anemia, cystic fibrosis, Thalassemia, and the like, and detection, evaluation, and/or characterization of polymorphism in genetic loci associated with various cancers such as p53, Ras, myc, associated with carcinomas, leukemias, sarcomas or the like.

Use of the method according to the present invention is exemplified by a system providing for rapid and accurate determination of a major histocompatibility complex class genotype of a subject in a sample (e.g., Class I or Class II). Most particularly, the method is directed to determining at least one HLA Class II gene locus including DRB1,..., DQB1,... DPB1 genes.]" See column 3, lines 56-68 and column 4, lines 1-7. Santamaria et al disclose "[The method is particularly well suited for Class II HLA typing, reducing costs, increasing its speed and especially improving its accuracy. As evidenced by the following Examples, sequence polymorphism analysis of

DRB1,...DQB1....and DPB1 genes can be rapidly performed in any subject of unknown HLA type.... The methodology of the present invention is envisioned to be useful for detailed analyses of the effects of sequence allelism at different Class II HLA loci on graft survival after allogenic transplantation. The method of the present invention allows rapid and precise sequence analysis of Class II HLA polymorphism in studies of human disease and may be of interest in the search for new Class II sequence variants in large populations of subjects."] See column 9, lines 60-68 and column 10, lines 1-16. In regards to the clinical measuring reagents described in instant claims 15 and 17, Santamaria et al disclose positions of polymorphic amino acid sequences that include at least one of DRB1 DQB1 and DPB1 genes of HLA and addresses variations of the base sequences. As a result, Santamaria et al disclose or suggest the clinical measuring reagents as claimed. See this entire document. Thus, Santamaria et al disclose or suggest the invention claimed except for addressing a marker.

However, with respect a marker as described in the instant claims, Santamaria et al disclose or suggest specific amino acid positions and base sequences that can be used for disease diagnosis including cancer. As a result, the Santamaria et al disclosure renders obvious the instant marker and the invention as presently claimed.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide methods for evaluating cancer treatments and clinical measuring reagents as claimed in the present invention because Santamaria et al disclose the method steps and starting reactants for diagnosing cancer and suggests treatments which renders obvious the invention as claimed.

5. Claims 1-10, 12, 14, 16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The Sasazuki et al reference (New Eng. Jour. Of Medicine, Vol. 339(17), pp1177-1185, Oct. 22,1998) addresses DR antigens in patients with"[... leukemia, lymphoma, marrow failure, or a congential disorder.]" and has been cited to further show the state of this art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LOUISE N. LEARY
PRIMARY EXAMINER

June 20, 2005